individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder.guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm or http://www.regulations.gov*.

Dated: January 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–936 Filed 1–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Draft Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) addressing the agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The draft guidance describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. The draft guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The draft guidance also addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the agency has not yet made a decision on approvability.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding the proposed collection of information, by March 23, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy Boocker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of FDAAA (Public Law 110–85). Section 914 of FDAAA added new section 505(q) to the act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the act. The draft guidance describes FDA's interpretation of section 505(q) of the act regarding how the agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA or a 505(b)(2) application. The draft guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition include a certification and (2) supplemental information or comments to a petition include a verification. Finally, the draft guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the agency has not yet made a decision on approvability.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on citizen petitions and petitions for stay of action that are subject to section 505(q) of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.

Description of Respondents: Respondents to this collection of information as it is related to citizen petitions are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups. Respondents to this collection of information as it is related to petitions for stay of agency action are persons who choose to file a petition for an administrative stay of action.

Burden Estimate: FDA is requesting public comment on estimates of annual submissions from these respondents, as required by section 505(q) of the act and described in this draft guidance. Section 505(q)(1)(H) of the act requires that citizen petitions and petitions for stay of agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the act requires that supplemental information or comments to such citizen petitions and petitions for stay of agency action include a verification to be accepted for review by FDA. The draft guidance describes our current thinking on the interpretation of these requirements. The draft guidance sets forth the criteria the agency will use in determining if the provisions of section 505(q) apply to a particular citizen petition or petition for stay of agency action. One of the criteria for a citizen petition or petition for stay of agency action to be subject to section 505(q) of the act is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, the draft guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the act. The draft guidance also recommends that if a petitioner submits a citizen petition or petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the act and the petitioner would like FDA to review the citizen petition or petition for stay of agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled, ''General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions'' (OMB Control Number 0910–0183). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b) (21 CFR 10.30(b))); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b) (21 CFR 10.35(b))); and (5) the submission of written comments on a filed petition for administrative stay of action (§ 10.35(c)). This information collection includes citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described above, that are subject to section 505(q) of the act and described in the draft guidance.

Under section 505(q) of the act and the draft guidance, the following information would be submitted to FDA but is not currently approved by OMB under the PRA:

1. The certification required under section 505(q)(1)(H) of the act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application. Although the submission of a certification for citizen petitions is approved under OMB Control Number 0910–0183, the certification would be broadened under section 505(q) of the act and the draft guidance.
2. The certification required under section 505(q)(1)(H) of the act for petitions for stay of action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application.
3. The verification required under section 505(q)(1)(I) of the act for comments to citizen petitions.
4. The verification required under section 505(q)(1)(I) of the act for comments to petitions for stay of agency action.
5. The verification required under section 505(q)(1)(I) of the act for supplements to citizen petitions.
6. Supplements to petitions for stay of agency action and the verification required under section 505(q)(1)(I) of the act.
7. The letter submitted by a petitioner withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the act.

Section 505(q)(1)(B) and (C) of the act and the draft guidance state that if FDA determines that a delay in approval of an ANDA or 505(b)(2) application is necessary based on a petition subject to section 505(q) of the act, the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB Control Number 0910–0001 (21 CFR 314.54, 314.94, and 314.102).

Based on FDA's knowledge of citizen petitions and petitions for stay of agency action subject to section 505(q) of the act that have been submitted since September 27, 2007, as well as the agency's familiarity with the time needed to prepare a certification and a

verification, our estimates for this information collection are as follows:

1. The certification currently submitted for a citizen petition would be broadened under section 505(q) of the act and the draft guidance. FDA estimates that it will receive annually approximately 25 certifications under section 505(q)(1)(H) of the act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application. FDA estimates that approximately 19 respondents will submit these certifications and that each certification will take approximately 30 minutes to prepare.

2. FDA estimates that it will receive annually approximately three certifications under section 505(q)(1)(H) of the act for petitions for stay of action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application. FDA estimates that approximately three respondents will submit these certifications and that each certification will take approximately 30 minutes to prepare.

3. FDA estimates that it will receive annually approximately 12 verifications required under section 505(q)(1)(I) of the act for comments to citizen petitions. FDA estimates that approximately nine respondents will submit these verifications, and that each verification will take approximately 30 minutes to prepare.

4. FDA estimates that it will receive annually approximately two verifications required under section 505(q)(1)(I) of the act for comments to petitions for stay of agency action. FDA estimates that approximately two respondents will submit these verifications and that each verification will take approximately 30 minutes to prepare.

5. FDA estimates that it will receive annually approximately 10 verifications required under section 505(q)(1)(I) of the act for supplements to citizen petitions. FDA estimates that approximately seven respondents will submit these verifications and that each verification will take approximately 30 minutes to prepare.

6. FDA estimates that it will receive annually approximately one supplement to petitions for stay of agency action as described under section 505(q)(1)(I) of the act, that approximately one respondent will submit this supplement, and that each supplement will take approximately 6 hours to prepare. FDA estimates that it will receive annually approximately one verification required under section 505(q)(1)(I) of the act for supplements to petitions for stay of agency action, that approximately one respondent will submit this verification, and that each verification will take approximately 30 minutes to prepare.

7. FDA estimates that it will receive annually approximately one letter from petitioners withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the act. FDA estimates that approximately one respondent will submit this letter and that the letter will take approximately 30 minutes to prepare.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Annual Frequency per Response	Total annual Responses	Hours per Response	Total Hours
Certification for citizen petitions	19	1.32	25	0.5	12.5
Certification for petitions for stay of agency action	3	1	3	0.5	1.5
Verification for comments to citizen petitions	9	1.33	12	0.5	6.0
Verification for comments to petitions for stay of agency action	2	1	2	0.5	1.0
Verification for supplements to citizen petitions	7	1.43	10	0.5	5.0
Supplements to petitions for stay of agency action and the verification for the supplement	1	1	1	6.5	6.5
Letter withdrawing a petition for stay of agency action	1	1	1	0.5	0.5
Total Hours					33.0

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information collection is 33 hours.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: January 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–937 Filed 1–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0224]

Final Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff: Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of a guidance for industry entitled ''Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff: Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007'' dated January 2009. The guidance provides sponsors, industry, researchers, investigators, and FDA staff with the agency's current thinking regarding the types of applications and submissions that sponsors, industry, researchers, and investigators submit to FDA and accompanying certifications as described in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD 20993–0002, 301–796–4830. Send one self addressed adhesive label to assist that office in processing your requests. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Office of Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Background

Title VIII of FDAAA, Public Law 110–85, amended the Public Health Service (PHS) Act by adding new section 402(j), 42 U.S.C. 282(j). The new provisions require that additional information be submitted to the clinical trials data bank (*www.ClinicalTrials.gov*) previously established by the National Institutes of Health (NIH)/National Library of Medicine (NLM), including expanded information on clinical trials and information regarding the results of clinical trials.

The purpose of Title VIII is to provide a means for ensuring that the public has access to information about certain clinical trials. Specifically, Title VIII is intended to provide a mechanism for the public to learn about clinical trials that are being conducted, as well as the results of those trials. One provision of Title VIII (section 401(j)(5)(B) of the PHS Act, 42 U.S.C. 282(j)(5)(B)) requires that a certification accompany certain human drug, biological product, and device applications and submissions to FDA.

The certification required under section 402(j)(5)(B) of the PHS Act (42 U.S.C. 282(j)(5)(B)) plays a role in helping to achieve the purposes of Title VIII of FDAAA. One purpose of the certification is to require the submitter to confirm that it has complied with all applicable requirements of Title VIII, including the requirement to register applicable clinical trials. ''Applicable clinical trial'' is defined at section 402(j)(1)(A)(i) of the PHS Act (42 U.S.C. 282(j)(1)(A)(i)). For additional information on this definition and other relevant definitions, visit the NIH Web site at *http://prsinfo.clinicaltrials.gov*.

Failure to submit a certification, knowingly submitting a false certification, failure to submit required clinical trial information, and submission of clinical trial information that is false or misleading are all, as added by Title VIII of FDAAA, prohibited acts under section 301(jj) of the Federal Food, Drug, and Cosmetic Act (the act). Requiring a certification to accompany certain applications and submissions submitted to FDA is, therefore, one way of encouraging compliance with the provisions of the law.

The certification also facilitates FDA's exercise of its responsibilities under the law. The certification requirement is critical to the agency's ability to determine whether the law has been complied with and whether an enforcement action is appropriate under any of the prohibited acts under section 301(jj) of the act. Additionally, section 402(j)(3)(F) of the PHS Act (42 U.S.C. 282(j)(3)(F)) requires FDA to notify the Director of NIH of certain actions taken on applications and reports that were accompanied by a certification. That notification alerts NIH to the fact that the responsible party must submit the results of the trials within a certain period of time, thereby enabling NIH to exercise its responsibilities under Title VIII. The information provided in the certification form also will help FDA assist NIH in ''linking'' information posted on FDA's Web site regarding certain FDA regulatory actions to specific applicable clinical trials included in the registry and results databases. This linking, using the information in the certification form, particularly the NCT (National Clinical Trial) number(s) required in the form, eventually will allow FDA to help the public more easily correlate various reports, medical reviews, advisories, health alerts, advisory committee actions, and other materials with specific applicable clinical trials registered with ClinicalTrials.gov and identified by the NCT number.

The certification requirement went into effect on December 26, 2007. To assist sponsors, industry, researchers, and investigators in complying with the requirement, FDA created a certification form, FDA Form 3674, OMB Control No. 0910–0616, to be used to satisfy the certification requirement. Since the provision went into effect, FDA has received numerous inquiries asking whether various kinds of information and documents that sponsors, industry, researchers, and investigators submit to